

REMARKS

Applicant acknowledges receipt of the Office Action dated July 14, 2006, in which the Examiner entered a rejection of claims 1-3, 6-13, and 16-20 under § 112, first paragraph and continued the rejection of the same claims as anticipated by U.S. Patent 4,634,446 to *Kristinsson*. Applicant has again amended the claims and respectfully traverses these rejections for the reasons set out below.

Preliminary Comment

Applicant would like call to the Examiner's attention the fact that the present application has been subject to four office action and an RCE. In each instance, Applicant has attempted to respond to the Examiner's rejection of claim 1. Further, the undersign has telephoned the Examiner in an attempt to determine language that would resolve the underlying issues.

Applicant has attached hereto an Appendix showing the amendments to claim 1 that relate to the recitation of the location of the axis, which is a structural limitation on the device. Applicants respectfully point out that ALL of the recitations submitted to date are supported by the specification as a whole and by the figures, which clearly illustrate the concept of the present prosthetic hip joint. Despite all this, no progress has been made. Applicant respectfully protests the inefficiency of this process.

The Examiner now suggests re-insertion of the terms "substantially" and "center of rotation" into the claims. Applicant would respectfully point out that there appears to be little difference, if any, between a hip joint axis that "*passes through the patient's natural hip joint*" and a hip joint axis that "*passes through the center of rotation of the patient's natural hip joint*." Nonetheless, Applicant has returned the phrase "center of rotation" to claims 1 and 11. Applicant has deliberately omitted the term "substantially," however, in order to make clear one of the distinctions over *Kristinsson*, namely that *Kristinsson* does not disclose a prosthesis having a joint that replaces the hip joint.

It appears that the Examiner has determined that the recitation regarding the joint axis that appears in claim 4 is acceptable. If the present amendments to claims 1 and 11 are not acceptable, therefore, Applicant proposes to amend those claims to recite instead that "the joint axis substantially coincides with the natural axis of rotation of the patient's natural leg when rotated in a sagittal plane," as recited in claim 4.

Throughout the prosecution of this case, Applicant has maintained that the Kristinsson reference does not anticipate or render obvious the present claims because Kristinsson does not teach a hip joint at all. The Kristinsson device DOES NOT provide a prosthetic hip and has no hip-like function during walking. As set out in the previous Response and discussed again below, the present claims contain several limitations that distinguish the claim over Kristinsson. These limitations are separate from the limitation regarding the placement of the joint axis. In maintaining his conclusory rejection of the claims as anticipated by Kristinsson, the Examiner appears to be completely overlooking or disregarding these recitations.

Applicant therefore respectfully requests that the Examiner carefully review ALL of the arguments below and point out which portion of Kristinsson satisfies each and every limitation of the rejected claims.

Rejection over *Kristinsson*

In support of the present rejection, the Examiner states:

“Kristinsson discloses a prosthetic hip comprising a socket (1), a mount (7), a joint axis (14), a first member (8), an upper leg end (9), a load arm (18 and 17), an extension stop member having two engaging means to prevent rotation of the first member to the socket.”

In making this rejection, the Examiner completely fails to consider or address any of the distinctions over Kristinsson that were argued in the previous response. These rejections are independent of the limitation that is subject to the § 112 rejection and suffice to distinguish the present claims over Kristinsson.

Specifically, claims 1 and 11 require:

- a) that the mount define a “hip joint axis,”
- b) that the mount pivotally support the upper end of the prosthetic leg “such that the prosthetic leg is pivotable about said hip joint axis during walking,” and
- c) that the mount be positioned on the socket “such that the hip joint axis substantially passes through center of rotation of the patient’s natural hip joint.”¹

¹ All of these amendments are supported by the Specification as-filed, e.g. at paragraphs [0002], [0006], [0007], [0021], and [0022].

Applicant respectfully submits that **any one of the elements a), b) or c) set out above is sufficient to distinguish over the teachings of *Kristinsson***. First, the device disclosed by *Kristinsson*, is merely a socket for a lower leg prosthesis, and does not include a “hip joint axis.” The only axes disclosed by *Kristinsson* are the two vertical axes 11 (figure 4) and 14 (figure 5A) and the horizontal axis 12 (figure 5A). With regard to these axes, *Kristinsson* states:

“FIGS. 3A and 3B show the sleeve of FIGS. 1 and 2 mounted on a lower leg prosthesis. For this purpose there is used a holder means 7 which is connected to an artificial knee joint 9 via a supporting rod or bar 8. The holder means 7 is provided with two arms 10 which partially surround the sleeve and are fastened to the brim 2. . . *The arms 10 are pivotable about substantially vertical axis 11, as is more clearly shown in FIG. 5, to enable the shape of the sleeve to adapt to changes in shape of the stump resulting from the varying loads acting thereon. The holder means 7 also permits the sleeve to be adjusted in a desired direction, by rotating the sleeve around an axis 12, whereat the sleeve may be set at a desired angle or inclination by means of setting screws 13. The sleeve may also be rotated about an axis 14 and, for example, locked by friction engagement between two serrated means.* (emphasis added).

Clearly, none of these rotating components functions as a “joint axis” as that term is used by applicant, namely an axis that simulates the functionality of a natural anatomical joint. Nonetheless, to clarify this distinction, the claims have been amended to require that the present device define a “hip joint axis.” *Kristinsson* simply does not teach or suggest any component defining a hip joint axis.²

In addition, claims 1 and 11 further now require that that the mount pivotally support the upper end of the prosthetic leg “such that the prosthetic leg is pivotable about said hip joint axis during walking.” *Kristinsson* does not teach or suggest any components that could be considered a “hip joint” about which the prosthetic leg is pivotable during walking. Thus, this is a further distinction over the teachings of *Kristinsson*.

Finally, and as Applicant has asserted before, *Kristinsson* does not teach or suggest a device that defines an axis that “passes through the patient’s natural hip joint.” None of the “axes” 11, 12 and 14 of *Kristinsson* passes through the patient’s natural hip joint.

² This especially true because *Kristinsson* relates to a socket for an “above-knee amputee” (Col. 1, ll 10-14), sometimes also called a “transfemoral amputee.” **Above-knee amputees retain their natural hip joint**, as well as the upper part of their femur, and therefore have no need for a prosthetic hip joint as currently claimed. By way of illustration this distinction, Applicant previously submitted the front page of US Patent 4,790,855, in which the patient’s femoral stump and natural hip are clearly visible. **By contrast, the present application is intended for use by patients who have no stump and therefore have no functioning hip**

For all of these reasons, Applicant respectfully submits that the amended claims are patentable over the art of record.

Allowable claims

Claims 4, 5, 14 and 15 remain allowable.

As mentioned above, if the present amendments to claims 1 and 4 are not acceptable, Applicant proposes to amend claims 1 and 4 to include claim 4's recitation regarding the joint axis.

Conclusion

Applicant respectfully submits that the present amendments place the claims in condition for allowance and therefore respectfully requests that the Examiner enter the amendments and reconsider and withdraw the rejections. If the Examiner has any questions regarding this matter, he is encouraged to telephone the undersigned at (713) 238-8043.

Respectfully submitted,



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